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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/729343 10/16/96 LEE

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EXAMINER

HM42/1008

ART-UNIT-003 KEY-PAPER NUMBER

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1615

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DATE MAILED: 10/08/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on JULY 16, 1998 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire THREE month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-7, 9-16, 21-26 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-7, 9-16, 21-26 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

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The request filed on July 16, 1998 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/729,343 is acceptable and a CPA has been established. An action on the CPA follows.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-16, 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rey et al., Lymposuim Abstract, 1993 or Eanes Calc. Tiss. Res. 5,133-145 or Eanes "Intermediate States In The Precipitation of Hydroxyapatite taken alone or together with Miwa et al. 4,429,961.

The "poorly crystalline apatitic calcium phosphate" of the claims cannot be distinguished from poorly crystalline hydroxyapatites disclosed in the cited Prior Art. Niwa et al. discloses CA/P ratio at col. 11, par. 1. The specification does not point out differences in structure by comparison to poorly crystalline HAP of the Prior Art and the claims do not express improved working properties. Thus, the

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working properties as claimed may be equivalent to working properties of the cited Prior Art HAP products, absent comparative showing to the contrary.

Claims 1-7, 9-16, 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tung 5,037,639 or Constantz et al. 5,053,212 or Chow et al. 5,542,973 each taken alone or together with Glimcher Phil. Trans. R. Soc. Lond. B (1984).

Poorly crystalline hydroxyapatite structures are known to the art as is clear from studies as those reported in Glimcher et al.

Thus, those skilled in the art would be able to prepare a poorly crystalline HAP as claimed using the primary reference techniques in which calcium salt solution and phosphate salt solution are confined. The instant specification working example procedures are noted. Does the Applicant allege a difference in physical structure of HAP product in comparison with HAP products of the primary references?

The data of X-ray absorptions of claim 7 is noted. The X-ray data of same may be typical of poorly crystalline HAP as described in the Glimcher Article, but

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the criticality of absorptions at these points has not been shown to be necessary to yield improved working properties.

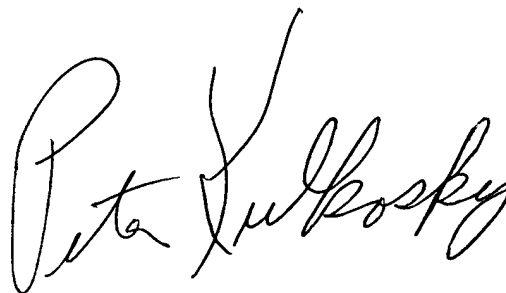
Claims 1-7, 9-16, 21-26 are rejected under 35 U.S.C. 112, pars. 1 and 2.

the claims describe a “poorly crystalline” material and this term is not descriptive of an improved “poorly crystalline” material.

The Applicants are requested to identify the crystalline apatitic calcium phosphate embodiments (i.e. working example product(s)) of the Prior Art of record which is closest in structure to the “poorly crystalline” apatitic calcium phosphate products of the invention.

KULKOSKY; aco

October 6, 1998

A handwritten signature in black ink, reading "Peter Kulkosky". The signature is written in a cursive, flowing style with a large initial "P".

PETER F. KULKOSKY
PRIMARY EXAMINER